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10/811,138	03/29/2004	Sylvia Daunert	50229-421	8471

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McDERMOTT WILL & EMERY LLP
600 13th Street, N.W.
Washington, DC 20005-3096

EXAMINER	
KOSSON, ROSANNE	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/811,138	DAUNERT ET AL.	
	Examiner	Art Unit	
	Rosanne Kosson	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-53* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 7 and 36-38, drawn to an isolated nucleic acid molecule encoding the protein of SEQ ID NO: 4 in which the amino acid at position no. 132 is isoleucine or a non-natural amino acid or phenylalanine, classified in class 536, subclass 23.1.

II. Claim 3, drawn to an isolated nucleic acid molecule encoding the protein of SEQ ID NO: 4 in which the amino acid at position no. 69 is cysteine, classified in class 536, subclass 23.1.

III. Claim 4, drawn to an isolated nucleic acid molecule encoding the protein of SEQ ID NO: 4 in which the amino acid at position no. 70 is cysteine, classified in class 536, subclass 23.1.

IV. Claim 5, drawn to an isolated nucleic acid molecule encoding the protein of SEQ ID NO: 4 in which the amino acid at position no. 74 is cysteine, classified in class 536, subclass 23.1.

V. Claim 6, drawn to an isolated nucleic acid molecule encoding the protein of SEQ ID NO: 4 in which the amino acid at position no. 76 is cysteine, classified in class 536, subclass 23.1.

VI. Claim 8, drawn to an isolated nucleic acid molecule encoding the protein of SEQ ID NO: 4 in which the amino acid at position no. 86 is tyrosine, classified in class 536, subclass 23.1.

VII. Claim 9, drawn to an isolated nucleic acid molecule encoding the protein of SEQ ID NO: 4 in which the amino acid at position no. 66 is cysteine, classified in class 536, subclass 23.1.

VIII. Claim 10, drawn to an isolated nucleic acid molecule encoding the protein of SEQ ID NO: 4 in which the amino acid at position no. 65 is cysteine, classified in class 536, subclass 23.1.

IX. Claim 11, drawn to an isolated nucleic acid molecule encoding the protein of SEQ ID NO: 4 in which the amino acid at position no. 16 is tyrosine, classified in class 536, subclass 23.1.

X. Claims 12 and 13, drawn to an isolated nucleic acid molecule encoding the protein of SEQ ID NO: 4 in which the amino acid at position no. 82 is tryptophan or phenylalanine, classified in class 536, subclass 23.1.

XI. Claims 14, 15, 20 and 23, drawn to a kit comprising the protein of SEQ ID NO: 4 in which the amino acid at position no. 132 is isoleucine or a non-natural amino acid or phenylalanine and a coelenterazine, classified in class 530, subclass 350. Claims 14 and 23 appear to be duplicate claims.

XII. Claims 16, 28 and 29, drawn to a kit comprising the protein of SEQ ID NO: 4 in which the amino acid at position no. 69 is cysteine and a coelenterazine, or to the protein of SEQ ID NO: 4 in which the amino acid at position no. 69 is cysteine, wherein this protein is conjugated to a fluorophore, classified in class 530, subclass 350.

XIII. Claims 17, 30 and 31, drawn to a kit comprising the protein of SEQ ID NO: 4 in which the amino acid at position no. 70 is cysteine and a coelenterazine, or to the protein of SEQ ID NO: 4 in which the amino acid at position no. 70 is cysteine,

wherein this protein is conjugated to a fluorophore, classified in class 530, subclass 350.

XIV. Claims 18, 32 and 33, drawn to a kit comprising the protein of SEQ ID NO: 4 in which the amino acid at position no. 74 is cysteine and a coelenterazine, to the protein of SEQ ID NO: 4 in which the amino acid at position no. 74 is cysteine, wherein this protein is conjugated to a fluorophore, classified in class 530, subclass 350.

XV. Claims 19, 34 and 35, drawn to a kit comprising the protein of SEQ ID NO: 4 in which the amino acid at position no. 76 is cysteine and a coelenterazine, or to the protein of SEQ ID NO: 4 in which the amino acid at position no. 76 is cysteine, wherein this protein is conjugated to a fluorophore, classified in class 530, subclass 350.

XVI. Claim 21, drawn to a kit comprising the protein of SEQ ID NO: 4 in which the amino acid at position no. 86 is tyrosine and a coelenterazine, classified in class 530, subclass 350.

XVII. Claim 22, drawn to a kit comprising the protein of SEQ ID NO: 4 in which the amino acid at position no. 66 is cysteine and a coelenterazine, classified in class 530, subclass 350.

XVIII. Claim 24, drawn to a kit comprising the protein of SEQ ID NO: 4 in which the amino acid at position no. 65 is cysteine and a coelenterazine, classified in class 530, subclass 350.

XIX. Claim 25, drawn to a kit comprising the protein of SEQ ID NO: 4 in which the amino acid at position no. 16 is tyrosine and a coelenterazine, classified in class 530, subclass 350.

XX. Claims 26 and 27, drawn to a kit comprising the protein of SEQ ID NO: 4 in which the amino acid at position no. 82 is tryptophan or phenylalanine and a coelenterazine, classified in class 530, subclass 350.

XXI. Claims 39-45, drawn to a method of identifying inhibitors of a bond-breaking enzyme (an HIV-1 protease), comprising immobilizing a fusion protein comprising the protein of SEQ ID NO: 4 in which the amino acid at position no. 132 is isoleucine or a non-natural amino acid or phenylalanine in two different loci, contacting the fusion protein at each locus with a candidate compound, and measuring the light emission intensities at each locus, classified in class 435, subclass 7.1.

XXII. Claims 39-43 and 45, drawn to a method of identifying inhibitors of a bond-breaking enzyme (an HIV-1 protease), comprising immobilizing a fusion protein comprising the protein of SEQ ID NO: 4 in which the amino acid at position no. 69 is cysteine in two different loci, contacting the fusion protein at each locus with a candidate compound, and measuring the light emission intensities at each locus, classified in class 435, subclass 7.1.

XXIII. Claims 39-43 and 45, drawn to a method of identifying inhibitors of a bond-breaking enzyme (an HIV-1 protease), comprising immobilizing a fusion protein comprising the protein of SEQ ID NO: 4 in which the amino acid at position no. 70 is cysteine in two different loci, contacting the fusion protein at each locus with a candidate compound, and measuring the light emission intensities at each locus, classified in class 435, subclass 7.1.

XXIV. Claims 39-43 and 45, drawn to a method of identifying inhibitors of a bond-breaking enzyme (an HIV-1 protease), comprising immobilizing a fusion protein

comprising the protein of SEQ ID NO: 4 in which the amino acid at position no. 74 is cysteine in two different loci, contacting the fusion protein at each locus with a candidate compound, and measuring the light emission intensities at each locus, classified in class 435, subclass 7.1.

XXV. Claims 39-43 and 45, drawn to a method of identifying inhibitors of a bond-breaking enzyme (an HIV-1 protease), comprising immobilizing a fusion protein comprising the protein of SEQ ID NO; 4 in which the amino acid at position no. 76 is cysteine in two different loci, contacting the fusion protein at each locus with a candidate compound, and measuring the light emission intensities at each locus, classified in class 435, subclass 7.1.

XXVI. Claims 39-43 and 45, drawn to a method of identifying inhibitors of a bond-breaking enzyme (an HIV-1 protease), comprising immobilizing a fusion protein comprising the protein of SEQ ID NO: 4 in which the amino acid at position no. 86 is tyrosine in two different loci, contacting the fusion protein at each locus with a candidate compound, and measuring the light emission intensities at each locus, classified in class 435, subclass 7.1.

XXVII. Claims 39-43 and 45, drawn to a method of identifying inhibitors of a bond-breaking enzyme (an HIV-1 protease), comprising immobilizing a fusion protein comprising the protein of SEQ ID NO: 4 in which the amino acid at position no. 66 is cysteine in two different loci, contacting the fusion protein at each locus with a candidate compound, and measuring the light emission intensities at each locus, classified in class 435, subclass 7.1.

XXVIII. Claims 39-43 and 45, drawn to a method of identifying inhibitors of a bond-breaking enzyme (an HIV-1 protease), comprising immobilizing a fusion protein

comprising the protein of SEQ ID NO: 4 in which the amino acid at position no. 65 is cysteine in two different loci, contacting the fusion protein at each locus with a candidate compound, and measuring the light emission intensities at each locus, classified in class 435, subclass 7.1.

XXIX. Claims 39-43 and 45, drawn to a method of identifying inhibitors of a bond-breaking enzyme (an HIV-1 protease), comprising immobilizing a fusion protein comprising the protein of SEQ ID NO: 4 in which the amino acid at position no. 16 is tyrosine in two different loci, contacting the fusion protein at each locus with a candidate compound, and measuring the light emission intensities at each locus, classified in class 435, subclass 7.1.

XXX. Claims 39-43 and 45, drawn to a method of identifying inhibitors of a bond-breaking enzyme (an HIV-1 protease), comprising immobilizing a fusion protein comprising the protein of SEQ ID NO: 4 in which the amino acid at position no. 82 is tryptophan or phenylalanine in two different loci, contacting the fusion protein at each locus with a candidate compound, and measuring the light emission intensities at each locus, classified in class 435, subclass 7.1.

XXXI. Claim 46, drawn to an isolated nucleic acid molecule encoding the protein of SEQ ID NO: 6 in which the amino acid at position nos. 51 and 75 is serine, classified in class 536, subclass 23.1.

XXXII. Claim 47, drawn to an isolated nucleic acid molecule encoding the protein of SEQ ID NO: 6 in which the amino acid at position nos. 67 and 75 is serine, classified in class 536, subclass 23.1.

XXXIII. Claim 48, drawn to an isolated nucleic acid molecule encoding the protein of SEQ ID NO: 6 in which the amino acid at position no. 151 is serine, classified in class 536, subclass 23.1.

XXXIV. Claim 49, drawn to a kit comprising the protein of SEQ ID NO: 6 in which the amino acid at position nos. 51 and 75 is serine and a coelenterazine, classified in class 530, subclass 350.

XXXV. Claim 50, drawn to a kit comprising the protein of SEQ ID NO: 6 in which the amino acid at position nos. 67 and 75 is serine and a coelenterazine, classified in class 530, subclass 350.

XXXVI. Claim 51, drawn to a kit comprising the protein of SEQ ID NO: 6 in which the amino acid at position no. 151 is serine and a coelenterazine, classified in class 530, subclass 350.

XXXVII. Claims 52 and 53, drawn to a method of identifying inhibitors of a bond-breaking enzyme (an HIV-1 protease), comprising immobilizing a fusion protein comprising the protein of SEQ ID NO: 6 in which the amino acid at position nos. 51 and 75 is serine in two different loci, contacting the fusion protein at each locus with a candidate compound, and measuring the light emission intensities at each locus, classified in class 435, subclass 7.1.

XXXVIII. Claims 52 and 53, drawn to a method of identifying inhibitors of a bond-breaking enzyme (an HIV-1 protease), comprising immobilizing a fusion protein comprising the protein of SEQ ID NO: 6 in which the amino acid at position nos. 67 and 75 is serine in two different loci, contacting the fusion protein at each locus with a candidate compound, and measuring the light emission intensities at each locus, classified in class 435, subclass 7.1.

XXXIX. Claims 52 and 53, drawn to a method of identifying inhibitors of a bond-breaking enzyme (an HIV-1 protease), comprising immobilizing a fusion protein comprising the protein of SEQ ID NO: 6 in which the amino acid at position no. 151 is serine in two different loci, contacting the fusion protein at each locus with a candidate compound, and measuring the light emission intensities at each locus, classified in class 435, subclass 7.1.

NOTES:

Regarding claims 36-38, these claims were placed in Group I because they depend from claim 2. But, they appear to contain an error, as a nucleic acid sequence cannot encode a non-natural amino acid. Applicants' intended meaning is not clear. Applicants are requested to revise these claims to correct the error. These claims may properly belong in a different group. The inventions are distinct, each from the other because of the following reasons.

Regarding claim 41, this claim recites a sequence that does not appear in the sequence listing. The sequence listing must be amended to include this sequence. Although this sequence is labeled SEQ ID NO: 5, SEQ ID NO: 5 is a polynucleotide of 662 bases. Appropriate correction of the claim and sequence listing required.

The inventions of Groups I-XX and XXXI-XXXVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the inventions of Groups I-X and XXXI-XXXIII are each drawn to a different polynucleotide, each having a different sequence and a different chemical structure. The inventions of Groups XI-XXI and XXXIV-XXXVI are each drawn to a different protein, each having a different chemical structure and chemical properties. The polynucleotide molecules are structurally and chemically different from the protein molecules, and each protein molecule may be made other than by

expressing the polynucleotide in a host cell. Each protein molecule may be made synthetically, particularly those proteins that contain non-natural amino acids. Therefore, the inventions of Groups I-XXI and XXXI-XXXVI are patentably distinct.

The inventions of Groups XXI-XXX and XXXVII-XXXIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the inventions of Groups XXI-XXX and XXXVII-XXXIX are each drawn to a different screening method, each method based on the reaction of a test compound with a different protein. Because each method uses a different reagent and measures a different chemical reaction, each of these methods is patentably distinct.

The inventions of Groups I-X and XXXI-XXXIII, inventions drawn to polynucleotides, and the inventions of Groups XXI-XXX and XXXVII-XXXIX, inventions to methods of identifying enzyme inhibitors, are unrelated because no polynucleotides are used in or required for these methods, which are based on the binding of test compounds to proteins. Therefore, these inventions are patentably distinct.

Inventions XI and XXI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the method of Group XXI may be practiced with a different product, as the protein in the kit (SEQ ID NO: 4 in which the amino acid at position no. 132 is isoleucine or a non-natural amino acid or phenylalanine) may be labeled with any label, including a fluorophore, or the loci may be labeled with any chromophore or fluorophore, or the unlabeled protein may be used as it is luminescent. Therefore, these inventions are patentably

distinct. Also, Group XI is not required for or used in any of the other methods, Groups XXII-XXX and XXXVII-XXXIX. Therefore, these inventions are patentably distinct.

Inventions XII and XXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the method of Group XXII may be practiced with a different product, as the protein in the kit (SEQ ID NO: 4 in which the amino acid at position no. 69 is cysteine) may be labeled with any label, including a fluorophore, or the loci may be labeled with any chromophore or fluorophore, or the unlabeled protein may be used as it is luminescent. Therefore, these inventions are patentably distinct. Also, Group XII is not required for or used in any of the other methods, Groups XXI, XXIII-XXX and XXXVII-XXXIX. Therefore, these inventions are patentably distinct.

Inventions XIII and XXIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the method of Group XXIII may be practiced with a different product, as the protein in the kit (SEQ ID NO: 4 in which the amino acid at position no. 70 is cysteine) may be labeled with any label, including a fluorophore, or the loci may be labeled with any chromophore or fluorophore, or the unlabeled protein may be used as it is luminescent. Therefore, these inventions are patentably distinct. Also, Group XIII is not required for or used in any of the other methods, Groups XXI, XXII, XXIV-XXX and XXXVII-XXXIX. Therefore, these inventions are patentably distinct.

Inventions XIV and XXIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the method of Group XXIV may be practiced with a different product, as the protein in the kit (SEQ ID NO: 4 in which the amino acid at position no. 74 is cysteine) may be labeled with any label, including a fluorophore, or the loci may be labeled with any chromophore or fluorophore, or the unlabeled protein may be used as it is luminescent. Therefore, these inventions are patentably distinct. Also, Group XIV is not required for or used in any of the other methods, Groups XXI-XXIII, XXV-XXX and XXXVII-XXXIX. Therefore, these inventions are patentably distinct.

Inventions XV and XXV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the method of Group XXV may be practiced with a different product, as the protein in the kit (SEQ ID NO: 4 in which the amino acid at position no. 76 is cysteine) may be labeled with any label, including a fluorophore, or the loci may be labeled with any chromophore or fluorophore, or the unlabeled protein may be used as it is luminescent. Therefore, these inventions are patentably distinct. Also, Group XV is not required for or used in any of the other methods, Groups XXI-XXIV, XXVI-XXX and XXXVII-XXXIX. Therefore, these inventions are patentably distinct.

Inventions XVI and XXVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using

the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the method of Group XXVI may be practiced with a different product, as the protein in the kit (SEQ ID NO: 4 in which the amino acid at position no. 86 is tyrosine) may be labeled with any label, including a fluorophore, or the loci may be labeled with any chromophore or fluorophore, or the unlabeled protein may be used as it is luminescent. Therefore, these inventions are patentably distinct. Also, Group XVI is not required for or used in any of the other methods, Groups XXI-XXV, XXVII-XXX and XXXVII-XXXIX. Therefore, these inventions are patentably distinct.

Inventions XVII and XXVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the method of Group XXVII may be practiced with a different product, as the protein in the kit (SEQ ID NO: 4 in which the amino acid at position no. 66 is cysteine) may be labeled with any label, including a fluorophore , or the loci may be labeled with any chromophore or fluorophore, or the unlabeled protein may be used as it is luminescent. Therefore, these inventions are patentably distinct. Also, Group XVII is not required for or used in any of the other methods, Groups XXI-XXVI, XXVIII-XXX and XXXVII-XXXIX. Therefore, these inventions are patentably distinct.

Inventions XVIII and XXVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See

MPEP § 806.05(h). In the instant case, the method of Group XXVIII may be practiced with a different product, as the protein in the kit (SEQ ID NO: 4 in which the amino acid at position no. 65 is cysteine) may be labeled with any label, including a fluorophore, or the loci may be labeled with any chromophore or fluorophore, or the unlabeled protein may be used as it is luminescent. Therefore, these inventions are patentably distinct. Also, Group XVIII is not required for or used in any of the other methods, Groups XXI-XXVII, XXIX, XXX and XXXVII-XXXIX. Therefore, these inventions are patentably distinct.

Inventions XIX and XXIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the method of Group XXIX may be practiced with a different product, as the protein in the kit (SEQ ID NO: 4 in which the amino acid at position no. 16 is tyrosine) may be labeled with any label, including a fluorophore, or the loci may be labeled with any chromophore or fluorophore, or the unlabeled protein may be used as it is luminescent. Therefore, these inventions are patentably distinct. Also, Group XIX is not required for or used in any of the other methods, Groups XXI-XXVIII, XXX and XXXVII-XXXIX. Therefore, these inventions are patentably distinct.

Inventions XX and XXX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the method of Group XXX may be practiced with a different product, as the protein in the kit (SEQ ID NO: 4 in which the amino acid at position no.

82 is tryptophan or phenylalanine) may be labeled with any label, including a fluorophore, or the loci may be labeled with any chromophore or fluorophore, or the unlabeled protein may be used as it is luminescent. Therefore, these inventions are patentably distinct. Also, Group XX is not required for or used in any of the other methods, Groups XXI-XXIX and XXXVII-XXXIX. Therefore, these inventions are patentably distinct.

Inventions XXXIV and XXXVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the method of Group XXXVIII may be practiced with a different product, as the protein in the kit (SEQ ID NO: 6 in which the amino acid at position nos. 51 and 75 is serine) may be labeled with any label, including a fluorophore, or the loci may be labeled with any chromophore or fluorophore, or the unlabeled protein may be used as it is luminescent. Therefore, these inventions are patentably distinct. Also, Group XXXIV is not required for or used in any of the other methods, Groups XXI-XXX, XXXVIII and XXXIX. Therefore, these inventions are patentably distinct.

Inventions XXXV and XXXVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the method of Group XXXV may be practiced with a different product, as the protein in the kit (SEQ ID NO: 6 in which the amino acid at position nos. 67 and 75 is serine) may be labeled with any label, including a fluorophore, or the loci may be labeled with any chromophore or fluorophore, or the unlabeled protein may

be used as it is luminescent. Therefore, these inventions are patentably distinct. Also, Group XXXV is not required for or used in any of the other methods, Groups XXI-XXX, XXXVII and XXXIX. Therefore, these inventions are patentably distinct.

Inventions XXXVI and XXXIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the method of Group XXXIX may be practiced with a different product, as the protein in the kit (SEQ ID NO: 6 in which the amino acid at position no. 151 is serine) may be labeled with any label, including a fluorophore, or the loci may be labeled with any chromophore or fluorophore, or the unlabeled protein may be used as it is luminescent. Therefore, these inventions are patentably distinct. Also, Group XXXVI is not required for or used in any of the other methods, Groups XXI-XXX, XXXVII and XXXVIII. Therefore, these inventions are patentably distinct.

Additionally, the searches for any one group are not required for and are not coextensive with the searches for any other group, thereby creating an undue burden of search and examination. The results from a search of each of these groups have different considerations with respect to the prior art. Burden lies not only in the search of U.S. patents, but also in the search for literature and foreign patents and in examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness, written description and enablement. Further, the different groups have each acquired a separate status in the art, as shown in part by their different classifications.

Applicants must choose **ONE** polypeptide or one polynucleotide from among those claimed as indicated in the different groups above. Each polypeptide and each polynucleotide

sequence is a distinct invention requiring separate searches. These are NOT species. Each sequence is a chemically, structurally and functionally distinct molecule. Therefore, the each of these polypeptides and each of these polynucleotides is patentably distinct.

Moreover, each sequence requires a separate set of searches. Applicants should note that searching each sequence imposes a serious search burden. Currently, there are approximately eight different databases that accompany the results of a search for one discrete amino acid or nucleic acid sequence, and each result set from a particular database must be carefully considered. Each set of prior art has its own considerations with respect to anticipation and obviousness. Hence, the search for even two different polypeptides or polynucleotides in the databases, in addition to searching the organic molecule databases, would require extensive searching and review. Therefore, these inventions are patentably distinct.

Additionally, this application contains claims directed to the following patentably distinct species of the claimed invention. The species are as follows.

a) If Applicants elect one of Groups XI-XX or XXXVIII-XXXX, Applicants must elect one of the coelenterazines listed in the elected claims, i.e., one of CTZ, i, ip, h, hcp, cp, fcp, f, n or native.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species in a) above for prosecution on the merits to which the claims shall be restricted if no linking claim is finally held to be allowable. The following claims are generic: 14-27 and 49-51.

Applicants are advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicants must indicate which are readable upon the elected species. MPEP § 809.02(a).

Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is clearly proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner, Art Unit 1653

MARYAM MONSHIPOURI, PH.D.
PRIMARY EXAMINER

rk/2006-07-21